The German Healthcare Sector

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SUMMARY

2004 was the first year after the German healthcare reform, the so-called "Statutory Health Insurance (SHI) Modernization Act." The reform led to uncertainty among both doctors and patients. It also had a substantial impact on the German medical industry and health care infrastructure. A rising number of Germans would like to take advantage of diagnostic therapeutic treatments. This is obstructed by the strained financial situation of the SHI. Thus, the German health ministry is facing the challenge of establishing what kind of medical services will continue to be covered by the SHI. "Health premiums" and "citizen insurance" are the two models currently discussed by German politicians.

In the long term, only a fundamental reorganization to a market-driven healthcare system with increased competition will guarantee affordable, high-quality healthcare.

THE GERMAN HEALTH CARE SYSTEM

The German health care system is facing tremendous challenges. As life expectancy rises, elderly people are requiring longer medical care and the number of elderly committed to hospitals or nursing homes because of geriatric disorders or chronic diseases is growing steadily. The changes in population size and structure in Germany over the past years have had a negative impact on the financing of the German social security system and herald more dramatic changes for the future.
In Germany, the term "health care system" encompasses all institutions and individuals who contribute to, support, and restore the health of the population. Federal and state governments are responsible for the maintenance of the public health care system; all insured persons receive health care benefits; and suppliers of such services are remunerated directly by the insurance funds.
Nearly 90% of the German population, or 72 million people, are insured in the statutory health insurance (SHI), the public sickness funds. In 2003, SHI's total expenditures amounted to EUR 144.5 billion.

MARKET OVERVIEW

Healthcare Reform

In 2004, the SHI Modernization Act (GKV-Modernisierungsgesetz – GMG) came into effect and temporarily relieved statutory health insurance funds of some of their financial. In the third quarter of 2004, sickness funds reported a surplus of some EUR 2.6 billion. The federal government's goal of decreasing SHI contribution rates to an average 13.6% by way of this reform failed. The surplus gained by the sickness funds was mostly spent on the reduction of their accumulated financial deficits, which amounted to EUR 8 billion in total. The positive development of the SHI funds' financial status was a result of increased co-payments of patients, e.g., the practice fee, and secondly, of restrictions in the provision of services and expenditures on pharmaceuticals. Expenditures on drugs decreased by EUR 2.4 billion in 2004 compared

to 2003, owing to the exclusion of non-prescription medications from reimbursement as well as to the manufacturer's rebate ("Herstellerrabatte").

Structural Measures within the SHI Modernization Act (GMG)
Medical care experts expect that the newly established Institute for Quality and Cost-Effectiveness in the Health Care System (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG) will substantially influence the design of future health care. One of the institute's tasks is the evaluation of medical diagnosis and treatment methods. The most significant changes for the quality of healthcare begin to emerge with the new provisions for integrated care, intended to break through the strict separation of healthcare sectors. By allocating 1% of physicians' fees or hospital budgets, respectively, to integrated care, the SHI Modernization Act provides an initial financing pool of EUR 680 million annually for the advancement of this tool. By December 2004, 239 integrated care contracts had been registered and 89 medical treatment centers had been approved.

2004: Mandatory DRG (Diagnosis Related Groups) Introduction
2004 was the last budget-neutral year for German acute care hospitals. The German flat-rate reimbursement catalogue (G-DRGs) encouraged hospitals to restructure. By the end of 2004, 86% of the 1,836 hospitals affected had changed to the DRG system. The change in hospital reimbursement also alters the structures of the German hospital landscape. Part of the inadequately funded municipal facilities were privatized by their operating institutions or sold to private operators. This did not even stop at maximum care providers such as university hospitals. The financial pressure on hospitals has been passed on to the medical technology companies. Procurement of medical devices has been standardized and streamlined by purchasing networks. The new catalogue is more complex than the previous one. It comprises 878 DRGs and 71 supplementary payments. Supplementary payments also include "emerging" medical technologies, which were not before.

Impacts on Innovation
If hospital-individual base rates are adjusted to a uniform national base rate, hospitals with a high base rate run the risk of losing out. This would particularly affect maximum care providers such as university hospitals, which for the most part use innovative, high-value medical technologies. An expert report recommended a differentiation of hospitals according to their levels of care and an extension of the convergence phase until the base rates are adequately adjusted. Parts of this recommendation, such as the extension of the convergence phase, have been included in the DRG amendment law.

Impacts of the SHI Modernization Act , in effect as of January 2004, had a particularly dramatic impact on the medical technical aids industry. In the first three quarters of 2004, this segment saw 13.7% decrease in expenditures. The share of technical aids in the SHI's total expenditures within this period of time amounted to only 3.18% – compared to 3.58% in the previous year. Meanwhile, co-payments, additional payments, nationwide reference prices, changes in reimbursement and the resulting difficulties have left their mark on patients and care providers. Some of the most significant problems in implementing the law are a result of vague phrasing in and differing interpretations of the law. This has led to substantial uncertainties among all participants in the medical technical aids market.

Low-Price Policy raises Question of Quality
The GMG caused extreme price cuts in the technical aids sector. Sickness funds, for instance, revoked existing contracts. Furthermore, an increasing number of care providers had to file for insolvency. Manufacturers were not spared the GMG's repercussions either. Due to the increased pressure on sales and prices, they had to accept sales decreases of up to 40% in 2004. This low-price policy harbors the risk of causing a decline in quality in the medium term. It is feared that care providers will not

be able to maintain their service in the present quality. Manufacturers are increasingly forced to relocate their production facilities to low- wage countries and/or reduce the high quality of their products to a sickness fund standard quality.

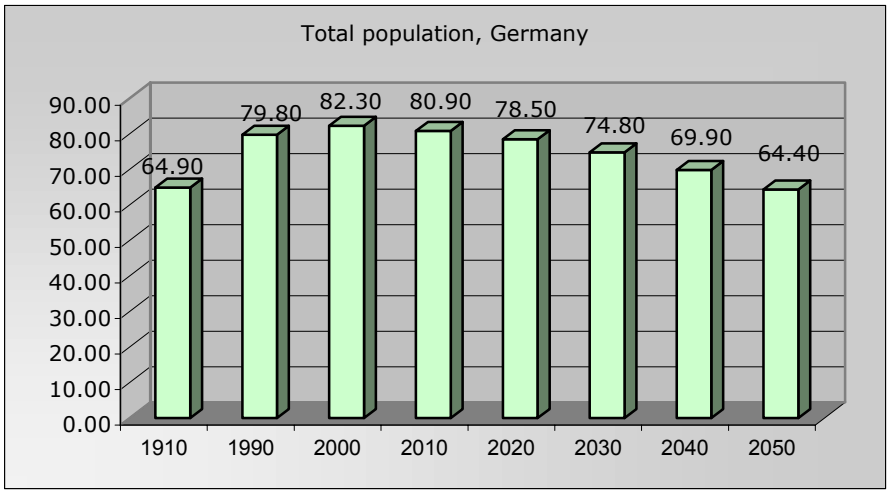
Federal Reference Prices
On 1 January 2005, federal reference prices for various product groups of the medical technical aids register ("Hilfsmittelverzeichnis-HMV") came into effect; including: arch supports; technical aids for compression therapy; visual and hearing aids; absorbing incontinence aids. It is planned to stipulate reference prices for 70 % of all medical technical aids. In total, 253 reference prices were set. 35 % of the prices were increased; 64 % remained at the same level.

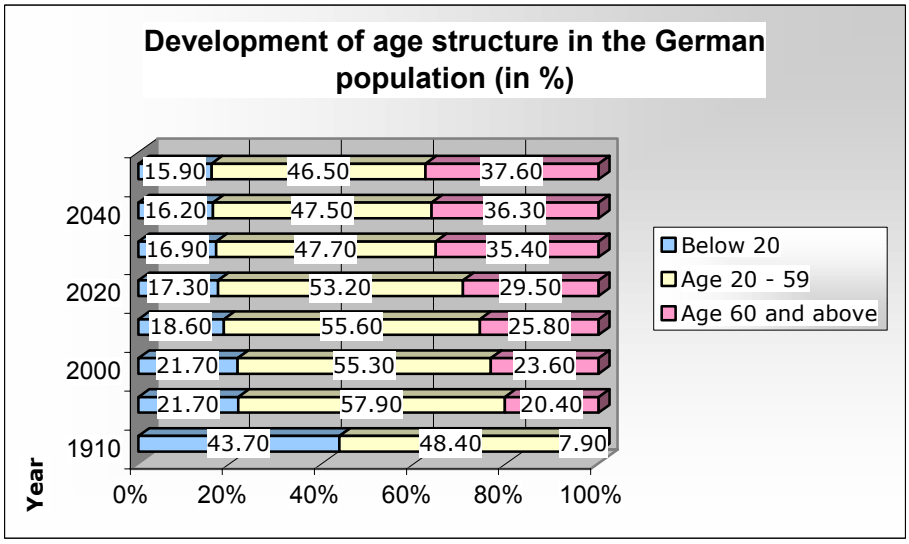
Increased Appreciation of Homecare
German legislative bodies and statutory health insurance funds are still not taking the growing significance of homecare into account. Homecare is characterized by the qualified and professional provision of advice and support on the use of technical aids, often in combination with drugs, dressing materials or medical devices that are sold exclusively by pharmacies. Homecare services are almost exclusively financed via product compensation, and the reimbursement of technical aids in particular. Decreasing reference prices and a price determination considering nothing but the cost of the product put this sector of healthcare, which represents a crucial link between the pure supply of products and the treatment and care of patients in their own home environment, increasingly at risk. The rising tendency towards flat-rate reimbursement also endangers customized patient care.

Pressure on Prices and Administration Costs
Small, local homecare companies particularly suffer from the severe price competition among care providers. They are faced with increasing administrative costs arising from co-payments; sickness fund individual reimbursement procedures; individual contracts rather than general agreements; participation in tenders. It is as yet unclear how the introduction of an electronic prescription planned for 2006, as part of an electronic health insurance card, would affect the homecare market. The implementation of the necessary technology will unquestionably result in considerable extra costs for care providers.

New Models of Care: Integrated Care and Medical Healthcare Centers
With the GMG, the development of new healthcare structures gained additional momentum. Legal requirements for the conclusion of integrated care agreements were deregulated and allow for individual agreements between sickness funds and care providers. Thus, homecare companies can now become contracting parties, too. Manufacturers can indirectly get involved in integrated care in the form of management companies. The start-up financing provided for by the GMG triggered a downright contracting race among sickness funds. More than 200 contracts were concluded in 2004. They differ significantly in terms of the character and extent of care agreed upon, the following healthcare areas predominant: Endoprosthetics; cardiovascular surgery; interventional cardiology /care for the chronically ill; coronary heart diseases; hospital-based outpatient care according to § 115b of the German Social Code, Book Five, and breast cancer diagnostics and therapy, mainly reimbursed via complex flat rates. In contrast to integrated care agreements, implementation of medical healthcare centers has started somewhat sluggishly. The law does not provide for the involvement of industry or trade. Nevertheless, it is apparent that many homecare companies and providers of health supplies perceive cooperation with medical healthcare centers as an important strategic market positioning tool.

Statistical Data

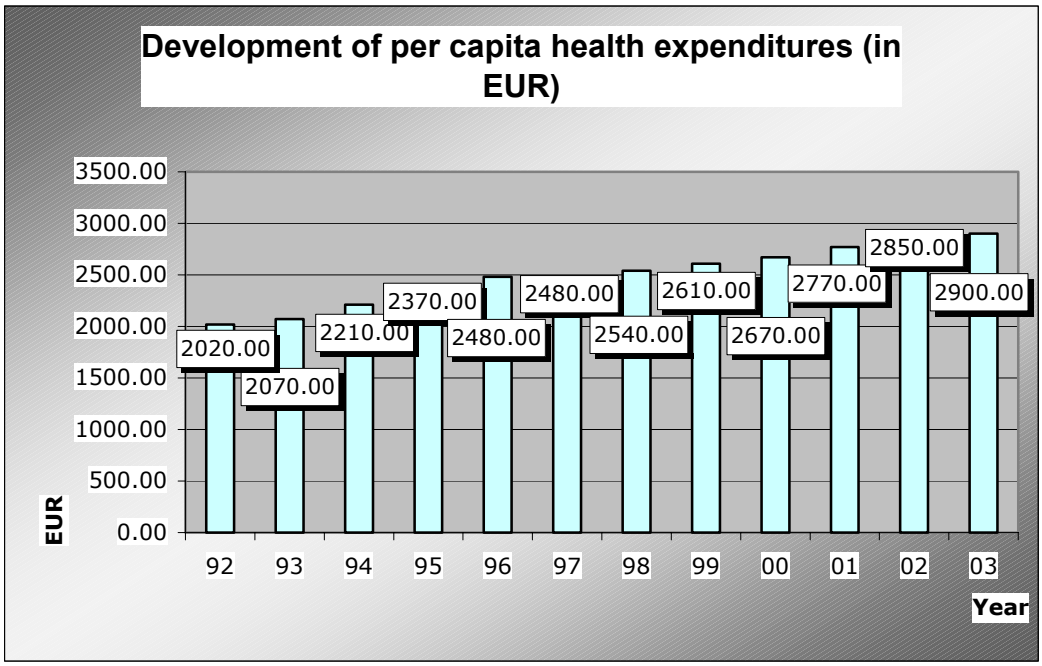




In 2003 (the year for which most recent official figures were provided by the Federal Statistical Office), expenditures in the health care sector amounted to EUR 239 billion compared to EUR 163 billion spent in 1992.

Gross domestic product (GDP) and health care expenditures – Germany

Year	GDP in EUR billion	Healthcare expenditures in EUR billion	Health care expenditures as % of GDP
1992	1,615	163	10.1
1993	1,648	168	10.2
1994	1,733	180	10.4
1995	1,796	194	10.8
1996	1,829	203	11.1
1997	1,871	204	10.9
1998	1,930	208	10.8
1999	1,984	214	10.8
2000	2,026	219	10.8
2001	2,065	227	11.0
2002	2,110	234	11.1
2003	2,130	239	11.2



The Statutory Health Insurance (SHI) accounts for approximately half of these annual expenditures. In 2003, for example, the SHI paid EUR 145 billion of total health care expenditures of EUR 239 billion.

Gross Domestic Product (GDP) and Statutory Health Insurance Expenditures (SHI)

Year	GDP in EUR billion	SHI Expenditures in EUR billion	SHI share in expenditures as % of GDP
1970	345	13	3.8
1980	754	46	6.1
1990	1,231	73	5.9
1995	1,769	124	7.0
1996	1,829	128	7.0
1997	1,871	125	6.7
1998	1,930	127	6.6
1999	1,984	131	6.6
2000	2,026	134	6.6
2001	2,065	139	6.7
2002	2,110	143	6.8
2003	2,130	145	6.8

Health care expenditures (2002) by large institutions:

EUR 9.6 billion (4.1%) - public and private sector employers;
EUR 18.4 billion (7.9%) - public administrations;
EUR 4.3 billion (1.8%) - the three German pension fund providers;
EUR 19.7 billion (8.4%) - private health insurance providers;
EUR 16.4 billion (7.0%) - nursing-care insurance ("Pflegeversicherung")
EUR 4.0 billion (1.7%) - statutory accident insurance;
EUR 28.5 billion (12.2%) – other public and private non-profit organizations

SHI expenditures 2003: in EUR billion

Sector	2002	2003	Growth Rate	Share of total SHI expenditures
hospital	46.152	46.845	1.5%	32.4%
sickness benefits ("Krankengeld")	7.56	6.968	-7.8%	4.8%
administration	8.019	8.038	0.2%	5.6%
others	14.062	13.165	-6.4%	9.1%
remedies + technical aids	9.304	9.257	-0.5%	6.4%
dentists / protheses	11.492	11.786	2.6%	8.2%
medication	23.44	24.196	3.2%	16.7%
medical therapy	22.309	24.276	8.8%	16.8%
Total	**142.338**	**144.531**	**1.5%**	

Health expenditures by type of benefit in EUR billion

Type of benefit	2001	2002	2003
Total benefits	227.788	234.967	239.703
Prevention/ Health Protection	10.329	10.728	11.096
Medical benefits	59.783	60.913	62.278
Custodial/therapeutic benefits	51.902	53.934	54.746
Balance consequences due to illness	4.467	4.668	4.823
Accommodation/catering	14.664	14.891	14.953
Commodities	60.479	62.370	64.142
Pharmaceuticals	35.004	36.591	37.547
Additives	12.076	12.308	12.746
Other medical equipment	7.385	7.596	7.669
Transportation	3.616	3.828	3.968
Administration	11.928	12.645	13.155
Research/Training/Investment	10.619	10.988	10.542

Beds and Patient Fluctuation Hospitals 1991 - 2003						
year	**Hospitals**		**patient fluctuation**			
	a total of	**Beds in use**	**number of cases**	**Charging and Occupancy days**	**average**	
					retention period	**beds efficiency**
	quantity		**in 1,000**		**in days**	**in %**
1991	2,411	665,565	14,577	204,204	14.0	84.1
1992	2,381	646,995	14,975	198,769	13.2	83.9
1993	2,354	628,658	15,191	190,741	12.5	83.1
1994	2,337	618,176	15,498	186,049	11.9	82.5
1995	2,325	609,123	15,931	182,627	11.4	82.1
1996	2,269	593,743	16,165	175,247	10.8	80.6
1997	2,258	580,425	16,429	171,837	10.4	81.1
1998	2,263	571,629	16,847	171,802	10.1	82.3
1999	2,252	565,268	17,093	169,696	9.9	82.2
2000	2,242	559,651	17,263	167,789	9.7	81.9
2001	2,240	552,680	17,325	163,536	9.4	81.1
2002	2,221	547,284	17,432	159,904	9.2	80.1
2003	2,197	541,901	17,296	153,518	8.9	77.6

Prevention, Beds and Patient Fluctuation Arrangement of Prevention and Rehabilitation 1991 - 2003						
year	Arrangement of Prevention or Rehabilitation		Patient Fluctuation			
	a total of	Beds in use	number of cases	care days	average	
					retention period	beds efficiency
	Quantity		in 1,000		in days	in %
1991	1,181	144,172	1,473	45,729	31.0	86.9
1992	1,209	149,910	1,575	48,833	31.0	89.0
1993	1,245	155,631	1,632	50,469	30.9	88.8
1994	1,329	172,675	1,765	55,069	31.2	87.4
1995	1,373	181,633	1,896	58,820	31.0	88.7
1996	1,404	189,888	1,917	57,839	30.2	83.2
1997	1,387	188,869	1,575	42,972	27.3	62.3
1998	1,395	190,967	1,746	46,107	26.4	66.1
1999	1,398	189,597	1,915	49,874	26.0	72.1
2000	1,393	189,822	2,046	52,852	25.8	76.1
2001	1,388	189,253	2,097	53,514	25.5	77.5
2002	1,343	184,635	2,041	52,107	25.5	77.3
2003	1,316	179,789	1,900	49,204	25.9	75.0

Tariffs, Import regulations

Official trade barriers, such as quotas, do not exist. The importation of dental products into Germany is duty-free. A 16% import-turnover Tax ("Einfuhrumsatzsteuer") must be paid at the port of entry, and is, in later distribution stages, passed on to the ultimate end-user in the form of the value-added tax (VAT or "Mehrwertsteuer" - MWSt). For customs clearance, a product label is required, which describes the use, origin and value of the product.

Trade restrictions and safety regulations

Although no trade restrictions or other non-tariff barriers (such as quotas) apply to the sale of imported health care service products or parts/accessories for healthcare services on the German market, all equipment used in healthcare servicing must comply with German (and/or European) safety regulations and technical standards.

All electrical equipment in Germany must be suitable for use with 220 Volt, 50 cycle electrical current. Since January 1, 1996, CE approval is mandatory for all products sold on the European market. By marking their products with the CE approval symbol, manufacturers guarantee that their products correspond to the EU guidelines for electrical and electronic devices.

Furthermore, electrical equipment should have VDE or TUEV-approval. A "UL" approval is not a substitute but is helpful in obtaining "GS/VDE," or "GS/TUEV" approval in Germany. "GS" stands for "geprüfte Sicherheit" (safety-tested). Although "GS" and the "VDE" (or "GS" and TUEV") marks are not required by law, they are highly recommended

for marketing electrical goods in Germany. These labels denote high product safety. German consumers look for these labels as Americans do for the "UL" mark.

The U.S. product safety testing institute Underwriters Laboratories (UL), the VDE Testing and Certification Institute, the TUEV Product Service, and the IMQ (Product and Quality System Certification in Italy) have formed a strategic alliance in the field of electromagnetic compatibility (EMC). The result of this co-operation has been an EMC test mark recognized worldwide. For manufacturers of electrical and electronic products, this co-operation has led to a considerable simplification of EMC testing. Through a single test carried out by one of these four partners, a product can now be awarded an international EMC mark, which replaces the national test marks in the major world markets of Europe, the United States, Japan and Australia (more information on http://www.intlemcmark.com).

Contact information for the two testing institutes VDE and TUEV:

VDE – Verband Deutscher Elektrotechniker e.V.
Prüf- und Zertifizierungsinstitut (VDE Testing Division)

Merianstraße 28
DE-63069 Offenbach
Tel 1: 49 69 8306-0
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Fax: 49 69 8306-555
Internet: www.vde.de or http://www.vde.de/vde_pi
E-Mail: vde-institut@vde.com

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Melville
Underwriters Laboratories Inc.
ICS Dept. 1285 Walt
Melville, Long Island
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Tel: 516-271-6200
Fax: 516-439-6071

Entela Inc.
3033 Madison Ave.
Grand Rapids, MI 49548
Tel: 616-247-0515
Fax: 616-574-9752
E-mail: thubbard@entela.com

Underwriters Laboratories Inc.
International Compliance Service
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TUEV Rheinland GmbH	**TUEV Süddeutschland Holding AG**	**TUEV NORD**
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TUEV in the United States

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USA
Tel.: 203-426-0888
Fax: 203-426-4009
E-mail: info@tuv.com
Internet: http://www.us.tuv.com (further U.S. offices of the TUEV can be found on this Website)

TRADE PROMOTION OPPORTUNITIES

FUSE

FUSE – Featuring U.S. Exporters: U.S. manufacturers looking for sales leads or potential sales representatives in Germany can list their products and services on the German-language version of the U.S. Commercial Service website, www.buyusa.gov/germany, which targets an audience of German importers, distributors and commercial buyers. It allows a search via keyword.

Commercial News USA

Commercial News USA is the official United States Department of Commerce showcase for American-made products and services. The catalog-style magazine is designed to help American companies promote products and services to buyers in more than 145 countries. Each issue reaches an estimated 400,000 readers worldwide.
For more information, please visit: www.thinkglobal.us

Major Trade Shows

In Germany trade fairs play a major role in product marketing. U.S. companies wishing to penetrate the German market often make their first approach at major trade fairs. For U.S. manufacturers and exporters wishing to sell in Germany (and in Europe) it is important to exhibit at one of Germany's major international fairs. Exhibiting at fairs can bring direct sales, but, more significantly, it can be one of the least expensive ways to test the market's receptivity. Further the strength and scope of the competition can be assessed and contacts with others "in the trade" can be established. From these contacts, U.S. companies can gather a great deal of valuable information about

marketing in Germany and Europe. The most suitable trade shows in the healthcare sector are:

MEDICA - World Forum for Medicine - International Trade Fair and Congress. With ComPaMED International Trade Fair for Components, Parts and Raw Materials for Medical Manufacturers.

Organizer :
Messe Düsseldorf GmbH
Messeplatz · 40474 Düsseldorf
Tel: +49-211-4560-01 · Fax: +49-211-4560-668
http://www.messe-duesseldorf.de
E-mail: info@messe-duesseldorf.de
Project team:
MEDICA Tel: +49-211-4560-529 · Fax: +49-211-4560-87529
E-mail: info@messe-duesseldorf.de · http://www.medica.de

In the United States:

Messe Düsseldorf North America
150 North Michigan Avenue,
Suite 2920
Chicago, IL 60601
Tel: +1 (312) 781 51 80 · Fax:+1 (312) 781 51 88
E-Mail: info@mdna.com
Website: http://www.mdna.com

REHACARE INTERNATIONAL - International Trade Fair for Those with Special Needs and Those Requiring Care

Organizer:
Messe Düsseldorf GmbH
Messeplatz · 40474 Düsseldorf
Tel: +49-211-4560-01 · Fax: +49-211-4560-668
http://www.messe-duesseldorf.de
E-mail: info@messe-duesseldorf.de
Project team:
Tel: +49-211-4560-900 · Fax: +49-211-4560-668
E-mail: info@messe-duesseldorf.de · http://www.rehacare.de

In the United States:

Messe Düsseldorf North America
150 North Michigan Avenue,
Suite 2920
Chicago, IL 60601
Tel:+1 (312) 781 51 80 · Fax:+1 (312) 781 51 88
E-Mail: info@mdna.com
Website: http://www.mdna.com

Altenpflege+ProPflege – Trade fair with convention for seniors care + therapy and professional patient care

Organizer:
NürnbergMesse GmbH
Messezentrum · 90471 Nürnberg
Tel: +49-911-8606-0 · Fax: +49-911-8606-8228
http://www.nuernbergmesse.de
E-mail: info@nuernbergmesse.de
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Tel: +49-911-8606-8642 · Fax: +49-911-8606-8259
E-mail: propflege@nuernbergmesse.de · http://www.propflege.info

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E-mail: conexpogrp@earthlink.net
http://www.concordexpogroup.com

ORTHOPAEDE + REHA TECHNIK - International trade fair and world convention for orthopedis and rehabilitation

Organizer:
Bundesinnungsverband für Orthopädie-Technik
Reinoldistr. 7-9 · 44135 Dortmund
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E-Mail: Leipzig-Tradeshows@gaccny.com · http://www.gaccny.com

EXPOPHARM - International Pharmaceutical Trade fair

Organizer:
Werbe- und Vertriebsges. Deutscher Apotheker mbH
Carl-Mannich-Straße 26 · 65760 Eschborn
Tel: +49-6196-928410 · Fax: +49-6196-928404
http://www.expopharm.de
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E-mail: expopharm@abda.de

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The U.S. Commercial Service Germany can be contacted via e-mail at: dusseldorf.office.box@mail.doc.gov website: http://www.buyusa.gov/germany/en/.

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